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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,808	08/17/2000	Marlene Belfort	454311-2201.1	6356

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,808

Applicant(s)

BELFORT ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14 and 16-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, and 16-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Applicants amendment filed December 3, 2003 have been received and entered. Claims 9, 15, and 34-72 have been canceled. Consequently, claims 1-8, 10-14, and 16-33 are pending in the instant application.

Claim Objections

1. The objection of claims 11-33 for being improper multiple dependent claims is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-8 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Additionally in view of Applicants amendment this rejection is applied to claims 11-14, and 16-33.

Applicants are asserting that claim 1 has been amended to insert the limitations of claim 15. Specifically, claim 1 has been amended to recite that the intein is a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutations or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation in a location corresponding to residue 67 of the full-length Mtu intein, by sequence homology.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of Applicants own specification. Specifically page 25 of the specification “defines” “sequence homology” as “the sequences are very similar.” Thus, Applicants claims encompass truncated Mtu inteins with the endonuclease domain deleted, and V67L and/or D422G mutations or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, or any mutein using the homology limitation which is “very similar” to the muteins recited above.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation is a location corresponding to residue 67 of the full-length Mtu intein, by sequence homology alone are insufficient to describe the genus.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

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Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.”

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The rejection of claims 1-8 and 10 under 35 U.S.C. 102(e) as being anticipated by Comb et al is maintained. Additionally in view of Applicants amendment, this rejection is also applied to claims 11-14, and 16-33.

Applicants are asserting that Comb does not teach, suggest or enable a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutations or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by sequence homology or any intein having a V to L mutation in a location corresponding to residue 67 of the full-length Mtu intein by sequence homology.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of Applicants claim language. Applicants claims recite a non-naturally occurring intein which is a truncated Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, by **sequence homology**... (Emphasis added).

Applicants specification, page 25, defines "Sequence homology" as having a common evolutionary origin, or that the sequences are very similar.

Given that the molecule disclosed by Comb is a non-naturally occurring intein which is "very similar" to a Mtu intein with the endonuclease domain deleted, and V67L and/or D422G mutation or any intein having a D to G mutation in a location corresponding to residue 422 of the full-length Mtu intein, the disclosure of Comb is deemed to anticipate the claimed invention. At a minimum the intein disclosed by Comb is deemed to have a common evolutionary origin given that they both share the same function.

For reasons of record as well as the reason set forth above, this rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
March 8, 2004